

REMARKS/ARGUMENTS

Claims 1, 4-12 and 14-28 are pending. By this amendment, claim 13 is cancelled without prejudice or disclaimer and the specification and claims 7 and 27 are amended. Claims 14-18 and 28 have been withdrawn from consideration as being drawn to a non-elected invention, the requirement having been traversed. Reconsideration in view of the above amendments and following remarks is respectfully requested.

The specification was objected to. Paragraph [0088] has been amended to obviate the objection. Reconsideration and withdrawal of the objection are respectfully requested.

Claims 7, 13, 19 and 25-27 were rejected under 35 U.S.C. § 102(e) over Palkon et al. (U.S. Patent 7,007,696) and claims 8-12 and 20-24 were rejected under 35 U.S.C. § 103(a) over Palkon et al. The rejections are respectfully traversed.

Claim 7 recites a nasal mask having a relatively rigid mask frame and a relatively softer cushion provided to the frame. The cushion comprises an outer membrane including a face-contact portion to form a seal with the patient; a frame connection portion opposite the face-contact portion; an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion; and an underlying rim positioned below the membrane. The membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient. The cushion includes a nasal bridge region, a top lip region, and two side regions. A projected area of the framed connection portion is generally larger than an area defined by the face-contact portion of the membrane.

Palkon et al. do not disclose or suggest an inwardly sloping or stepped outer wall between the membranes 46, 47 and 48 and the frame engaging portion 32 of the cushion 30. As clearly shown, for example, in Figures 6 and 7 of Palkon et al., the side wall 45 extends perpendicularly

to the frame engaging portion 32. The side wall 45 of Palkon et al. is neither inwardly sloped or inwardly stepped. The side wall of the embodiments shown in Figures 8 and 9 of Palkon et al. also is not inwardly sloped or inwardly stepped.

With respect to the embodiments shown in Figures 10A-11 of Palkon et al., the side wall 150 is neither inwardly sloped nor inwardly stepped. In fact, it is respectfully submitted that as clearly shown in Figures 10A-11 the other than straight portion 151 of the side wall 150 actually extends outwardly from the frame connection portion.

As Palkon et al. do not disclose or suggest each and every feature of claim 7, the rejection fails to present a *prima facie* case of anticipation.

With respect to the rejection of claims 8-12 and 20-24, it is respectfully submitted that the Office Action's reliance on In re Aller, 105 USPQ 233 (CCPA 1955), fails to establish a *prima facie* case of obviousness.

As stated in M.P.E.P. §2144.04, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the Examiner may use the rationale used by the court. It is respectfully submitted that the facts In re Aller are not sufficiently similar to those of the instant application to permit the Examiner to rely on the rationale used by the court. Moreover, M.P.E.P. §2144.04 states that if the applicant has demonstrated the criticality of a specific limitation, it is not appropriate to rely solely on case law as the rationale to support an obviousness rejection. It is respectfully submitted that the criticality of the dimensions recited in claims 8-12 and 20-24 has been sufficiently demonstrated in the instant application as originally filed, and as discussed throughout the previous responses filed by applicant.

It is further respectfully noted that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the

determination of the optimum or workable ranges of the variable may be characterized as routine experimentation. See M.P.E.P §2144.05(II).B and its discussion of In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

In re Aller involved a claimed process which was performed at a temperature between 40 °C and 80 °C and an acid concentration between 25% and 70%. The claimed invention was held to be *prima facie* obvious over a reference which disclosed a process performed at a temperature of 100 °C and an acid concentration of 10%. The court held, “the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”

It is respectfully submitted that the facts of In re Aller are not sufficiently similar to the instant application because Palkon et al. do not disclose or suggest the general conditions of claims 8-12 and 20-24, nor do Palkon et al. disclose or suggest any of the dimensions recited in claims 8-12 and 20-24, nor any ranges of dimensions for the features recited in claims 8-12 and 20-24.

It is also respectfully submitted that Palkon et al. do not disclose or suggest that any of the dimensions recited in claims 8-12 and 20-24 are result-effective variables. Palkon et al. disclose that the thickness of the membranes 46, 47 and 48 of the nasal bridge region 38 of the cushion 30 are a significant feature of the invention and provide a significant improvement in the comfort of the cushion 30. See column 4, lines 44-47. Palkon et al. also disclose that the length of the sidewall portion 45A provides an improved angle of contact when the cushion 30A is worn by a user. Accordingly, the only result-effective variables recognized by Palkon et al. are the thickness of the membrane and the length of the sidewall portions of the cushion. Palkon et

al. do not recognize that a width of the membrane orifice or the membrane height is a result-effective variable. Accordingly, it would not have been obvious to one of ordinary skill in the art to modify Palkon et al. to arrive at the dimensions recited in claim 8. As another example, claim 9 recites the dimensions of the rim aperture and an effective height of the rim, and an effective ridge depth of the rim. As Palkon et al. do not recognize any of these features to be a result-effective variable, claim 9 would not have been obvious to one of ordinary skill in the art.

Claims 10, 11 and 18-24 recite additional dimensions of various claimed features of the application, none of which are recognized as result-effective variables by Palkon et al. Accordingly, each of claims 10, 11 and 18-24 are non-obvious over Palkon et al.

Claim 12 recites additional features of the invention and is allowable for the same reasons discussed above and for the additional features recited therein.

Reconsideration and withdrawal of the rejections over Palkon et al. are respectfully requested.

In view of the above amendments and remarks, applicants respectfully submit that all of the claims are allowable and that the entire application is in condition for allowance.

Should the Examiner believe that anything further is necessary to place the application in condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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